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Oridion

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6. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

6.1.1. Product name

PROPRIETARY:
Microstream External Battery Charger

COMMON:
Caponograph External battery Charger

:

6.1.2. Establishment registration number

Establishment registration number: 8044004

6.1.3. Establishment Address:

ORIDION MEDICAL 1987 LTD.
HAR HOTZVIM SCIENCE BASED INDUSTRIAL PARK
POB 45025
91450 JERUSALEM, ISRAEL

6.1.4. Device Listing Fda Form 2892:

A 733250

6.1.5. Product classification

The Microstream External Battery Charger is used as an accessory to Oridion's Microcap Capnograph (K981114) and NBP-75 (K964239) and is therefore classified as Class II according to 21CFR868.1400 (73CCK)

6.1.6. Intended use:

The Microstream External Battery Charger charges (off line) the battery pack used in Oridion's Microcap Capnograph (K981114) and NBP-75 (K964239) when the battery pack is removed from Oridion's Microcap Capnograph (K981114) and NBP-75 (K964239). The charger is never connected directly to the Capnograph.

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6.1.7. DEVICE DESCRIPTION

The Microstream External battery Charger is used when the battery pack used in Oridion's Microcap Capnograph (K981114) and NBP-75 (K964239) has a low charge and has been removed from the Capnograph. Additionally it is used to charge a spare back up battery. The charger is powered by a Universal Power supply (100VAC-240VAC Input, 22VDC-27VDC Output). The charger has a plastic case and 3 indicating light to signal the charging cycle condition. The charger is specifically designed to accept the battery pack from in Oridion's Microcap Capnograph (K981114) and NBP-75 (K964239).

6.1.8. Substantial equivalence:

The Microstream external battery charger is essentially equivalent in design, technology indications for use and intended use with the charger built into Oridion's Microcap Capnograph (K981114) and NBP-75 (K964239). The main difference is that the Microstream external battery charger charges the battery with battery pack out of the capnograph while the charger integrated into the Microcap Capnograph (K981114) and NBP-75 (K964239) charges the battery pack while the battery pack is in the capnograph.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2001

Mr. Sanford Brown
Oridion Medical 1987 Ltd.
P.O. Box 45025
Jerusalem 91450
ISRAEL

Re: K002163
Microstream External Battery Charger
Regulatory Class: II (two)
Product Code: 73 CCK
Dated: October 30, 2000
Received: November 3, 2000

Dear Mr. Brown:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Stephen Rhodes

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Oridion

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July 10, 2000

3. INDICATIONS FOR USE

510(k) Number (if known): K002163

Device Name:

Indications For Use:

If the battery pack used in Oridion's Microcap Capnograph (K981114) and NBP-75 (K964239) has a low charge and has been removed from the Capnograph. Additionally it is used to charge a spare back up battery.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002163